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A Pharmacovigilance study on anti-tubercular medications in the department of chest and tuberculosis of Tertiary care hospital

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ABSTRACT
Introduction: Tuberculosis has been one of the common diseases in human communities during the past 40 years. It has been reported by World Health Organization (WHO) that one third of the world's population is infected with Mycobacterium tuberculosis resulting in 8.4 million new tuberculosis cases in 1999.1 this high incidence of infection has caused a large number of morbidity and mortality which is partly due to serious adverse reactions induced by Anti-TB drugs. **Aim:** The study aimed to assess Pharmacovigilance study on Anti Tubercular Medications in the Department of Chest & Tuberculosis of a Tertiary Care Hospital. **Methodology:** A regular ward round participation was carried out in the department of Chest & TB. All the information's of patients was recorded. During data collection patients were informed about the study using patient information format and obtained their written consent either from the patients or their caregivers. **Results:** The results of the study showed that the incidence of all major adverse effects was 1.48 per 100 person's month of exposure. The occurrence of any major side effect in the study was associated with female sex. It does appear that with Anti-TB drugs used in this study the rate of ADRs increases with increased age. In our study the major cause of admission was adverse drug reactions in 15.9% of patients. In our study Hepatitis was observed in 25 (25.77%) patients, leading to the death of 2 patients. **Conclusion:** Anti-TB drugs could cause significant adverse effects both in quantity and severity. These reactions may lead to hospitalization, prolonged hospital stay and even death.
Keywords: Tuberculosis, Pharmacovigilance, Anti Tubercular Medications, Hospitalization, Death.

Introduction

Pharmacovigilance is an arm of patient care and surveillance. It aims at getting the best outcome from treatment with medicines. No one wants to harm patients, but unfortunately, for many different reasons, any medicine will sometimes do this. Good pharmacovigilance will identify the risks within the shortest possible time after the medicine has been marketed and will help to establish or identify risk factors. When communicated effectively, this information allows for intelligent, evidence-based prescribing with the potential for preventing many ADRs. Such information will ultimately help each patient to receive optimum therapy at a lower cost to the health system [1-2].

World Health Organization defines Pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. For reporting purposes, FDA categorizes a serious adverse event (events relating to drugs or devices) as one in which "the patient outcome is death, life-threatening (real risk of dying), hospitalization (initial or prolonged), disability (significant, persistent, or permanent), congenital anomaly, or required intervention to prevent permanent impairment or damage. There are few recent reports on epidemiology of ADRs. The detection of adverse drug reactions (ADRs) has become increasingly significant because of introduction of a large number of potent toxic chemicals as drugs in the last two or three decades. In India there are very few active ADRs monitoring centers and a lot effort is required in order to collect ADR data which may generate from safety surveillance of billions of therapeutically active substances either alone or in combinations. Tuberculosis has been one of the common diseases in human communities during the past 40 years. It has been reported by World Health Organization that one third of world population is infected with Mycobacterium tuberculosis resulting in 8.4 million new tuberculosis cases in 1999.10This high incidence of infection has caused a large number of morbidity and mortality which is partly due to serious adverse reactions induced by Anti TB drugs [3-5].

Most of the medicines used to treat tuberculosis today have been on the market for several decades. Clinicians treating TB patients around the world know these medicines well, and are usually well aware of their associated adverse drug reactions. The occurrence of these reactions is known to be frequent. The TB patient on treatment is taking more than one anti-TB medicine simultaneously and regimens last from many months to 2 years or more. This increases the likelihood of ADRs, some of which are severe. Most patients on treatment for drug-resistant TB experience at least one side-effect, and a recent study has shown that two thirds of such patients have had at least one medicine stopped temporarily or permanently as a result of ADRs.

These events may damage public confidence in any national treatment programme and affect patient adherence. Patients who stop taking anti-TB medicines pose a risk to themselves and to others. So why should TB practitioners today reflect on a more systematic approach to surveillance of drug-related problems, which is at the heart of pharmacovigilance. Firstly, while national TB programmes are generally well structured to monitor patients and have a long tradition of following up care using standardized indicators, they do not collect information on ADRs directly. It is therefore difficult to assess precisely the net benefit of a treatment programme if adversities related to the medicines used are not factored in. The contribution of ADRs to death, treatment default and failure can therefore only be conjectured. Secondly, the widespread recognition by health workers that anti-TB medicines often cause ADRs is poorly reflected in the published information on the subject. There is a dearth of published literature about anti-TB drug-induced mortality, morbidity and reduced quality of life, particularly in low-resource settings.

The overall burden of adversity directly attributable to anti-TB medicines is poorly quantified and it is not usually well profiled in individual TB control programmes. Thirdly, with the increasing use worldwide of more extensive regimens for drug-resistant TB, the added use of antiretroviral's (ARVs) in patients with HIV associated TB, and the imminent advent of new classes of medicines to treat TB, the case for improved pharmacovigilance becomes even stronger. Pharmacovigilance needs to be an integral accompaniment to treatment programmes as they expand their geographical coverage, given that the frequency and expression of ADRs may be influenced by factors linked to the demographic, genetic and nutritional patterns, and to the background co-morbidity (e.g. TB/HIV) in a population [6-9].

Tuberculosis has been one of the common diseases in human communities during the past 40 years. It has been reported by World Health Organization that one third of world population is infected with Mycobacterium tuberculosis resulting in 8.4 million new tuberculosis cases in 1999.10This high incidence of infection has caused a large number of morbidity and mortality which is partly due to serious adverse reactions induced by Anti TB drugs. Tuberculosis is an infectious disease caused by Mycobacterium tuberculosis. The disease spreads by droplet infection. Every untreated sputum positive patient spreads the disease to 10 to 15 persons per year. Every year approx. 18 lakhs people develop TB and 4 lakhs die from it. India is the highest TB burden country accounting more than one fifth of the global incidence [10-14]. Global annual incidence = 9.23 million, India annual incidence = 1.96 million. India is 17th among 22 High Burden Countries (in terms of TB incidence rate).

Tuberculosis is responsible for over 2 million deaths annually. The human immunodeficiency virus type 1 (HIV-1) epidemic has significantly contributed to the resurgence of TB worldwide, with HIV-1 infection being the most potent risk factor for the development of active TB. The emergence of multi–drug-resistant TB is a worldwide problem and threatens efforts to control the disease [15-16].

Methodology

Site of Study The study entitled "A Pharmacovigilance Examination on Anti Tubercular Medications in the Department of Chest & Tuberculosis of a Tertiary Care Hospital" was carried out in a 200 bedded tertiary care hospital located at Nellore, Andhra Pradesh.

Design of Patient Information Form

A patient information form has been prepared, to inform the patients or the care givers about the purpose and the necessity of the study by providing the patient information form and assured them that the confidentiality will be strictly maintained and also it will help the betterment of patients' health. The format includes the details like Department address, name and signature of the investigator and supervisor, date, place and details of the study.

Patient Consent Form: A patient consent form has also been prepared and written consent was collected from all the patients or from the caregivers by using patient consent form after providing the information format. The format contains details like address, date, place, provision for signature of the patient or caregivers, investigator and supervisor.

Data Entry Form:

A separate data entry form for incorporating inpatient details were designed and the format contains provision to enter the details such as name, age, sex, height, weight, IP. No, date of admission, date of discharge, vital signs, reason for admission, past medical history, past medication history, and any predisposing factors. Provision was given in the format for entry of details like Blood sugar levels, Blood counts, Liver function test, Renal function test, Electrolytes, Urine examination, Lipid profile, Diagnosis, Drug chart, ADR monitoring chart and Drug interaction chart and dose and any interventions.

Data Collection:

A regular ward round participation was carried out in the department of Chest & TB. All the information's of patients was recorded. During data collection patients were informed about the study using patient information format and obtained their written consent either from the patients or their caregivers.

Inclusion Criteria

All patients of either sex who were getting admitted to the study site during study period with pulmonary TB.

Exclusion Criteria

- Patients with chronic hepatitis illness such as cirrhosis, chronic hepatitis and acute viral hepatitis were excluded.
- The patients who all are unwilling to participate in the study and terminally ill will not included in the study.

Data Analysis

The obtained data will be thoroughly analyzed to evaluate the appropriateness of antitubercular drug use.

Sources: Causality and severity of reactions, determined using Naranjo Algorithm and Hartwig questionnaire as standard.

Results

During the 06 months study period 100 patients were diagnosed with positive TB. These patients were put on routine treatment protocol. Of these patients, 53 (53%) developed at least one adverse drug reaction. Total number of 97 adverse drug reactions detected in this study. The 53 patients with ADR

consisted of 13 females and 40 males. Occurrence of adverse reactions led to prolongation in hospital stay for 31 (59%) patients. The rate of adverse reactions was various in different age groups. It does appear that with Anti-TB drugs used in this study the rate of ADRs increases with increased age (Table 1).

Table 1: Anti-TB induced adverse drug reactions in different age groups

S.No	Age groups	Patients	Patients with ADR
01	0 – 10 years	0	0
02	11 – 20 years	05	03
03	21 – 30 years	18	09
04	31 – 40 years	16	10
05	41 – 50 years	21	10
06	51 – 60 years	27	12
07	>60 years	13	09
Total		100	53

The most frequent system – organ classes affected by ADRs were liver and biliary system and gastrointestinal system (36.08%) and gastrointestinal system (20.62%) (Table 2). The most serious adverse reaction was hepatitis (25.77%), leading to death in two patients (Table 3). In this study, 36 (37.11%) patients have shown the raise in liver transaminases. However only 3 patients developed increased enzymes level less than 3 times the base line. Furthermore, these patients didn't show any clinical or biochemical evidence of hepatotoxicity. Increasing in plasma uric acid was observed in 4 patients (4.12%) due to pyrazinamide. These reactions occurred in average 26.7 days after the beginning of treatment and followed by arthritis. After discontinuing of Pyrazinamide, the level of uric acid returned to normal range within 10 days (2.1 – 8.5 mg/dl). Isoniazid caused reactions such as constipation (17.53%), and peripheral neuropathy (6.20%), while rifampicin was the major cause of headache (8.25%), rash and pruritus (5.15%) and diarrhoea (4.12%).

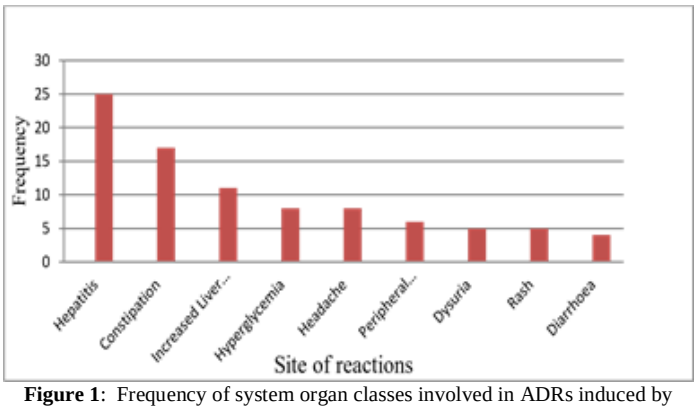

Figure 1: Frequency of system organ classes involved in ADRs induced by Anti – TB drugs

Table 2: Frequency of system organ classes involved in ADRs induced by Anti – TB drugs.

S.No	Site of reactions	Frequency	Percentage (%)
01	Liver and biliary system disorders	35	36.08
02	Gastrointestinal system disorders	20	20.62
03	Central & peripheral system disorders	14	14.43
04	Metabolic & nutritional disorders	08	8.24
05	Skin & appendage disorders	05	5.15
06	Urinary system disorders	05	5.15
07	Musculo-skeletal system disorders	04	4.12
08	Platelet, bleeding & clotting disorders	03	3.09
09	Vision disorders	03	3.09
	Total	97	100

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Table 3: Type of detected ADRs induced by Anti-TB drugs

S.No	Reaction	Frequency	(%)
01	Hepatitis	25	25.77
02	Constipation	17	17.53
03	Increased Liver Transaminases	11	11.34
04	Hyperglycemia	08	8.25
05	Headache	08	8.25
06	Peripheral Neuropathy	06	6.20
07	Dysuria	05	5.15
08	Rash	05	5.15
09	Diarrhoea	04	4.12
10	Increased Uric Acid	04	4.12
11	Vision Abnormality	02	2.06
12	Prolonged PT	02	2.06
	Total	97	100

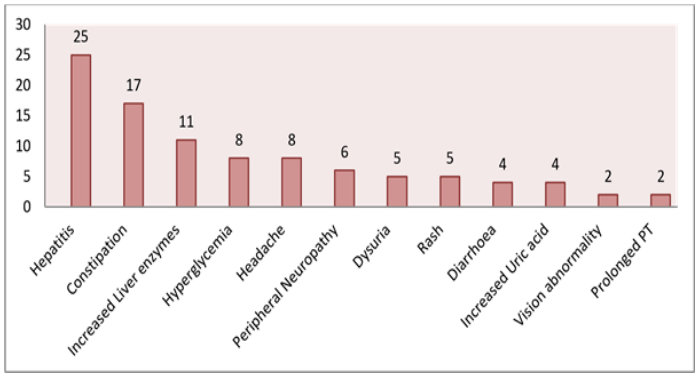

Figure 2. Type of detected ADRs induced by Anti-TB drugs

The only adverse reaction suspected to be induced by Ethambutol was vision abnormality such as blurred vision and burning eyes in two patients (2.06). The main action taken in patients with detected ADR was discontinuation of drug regimen (35.05%). The action mainly was taken when hepatotoxicity was detected. There was no specific treatment for alleviating the adverse reactions, other than headache and constipation. The causality assessment of ADRs revealed that 8 (8.2%) cases were detected as certain, 43 (44.33) as possible and 46 (47.42) as probable reactions (Table 4).

Table 4. Causality of ADRs induced by Anti-TB drugs according to Naranjo algorithm

S.No	Scale	Percent	Frequency
01	Probable	47.42	46
02	Possible	44.33	43
03	Certain	8.2	08
Total		100	97

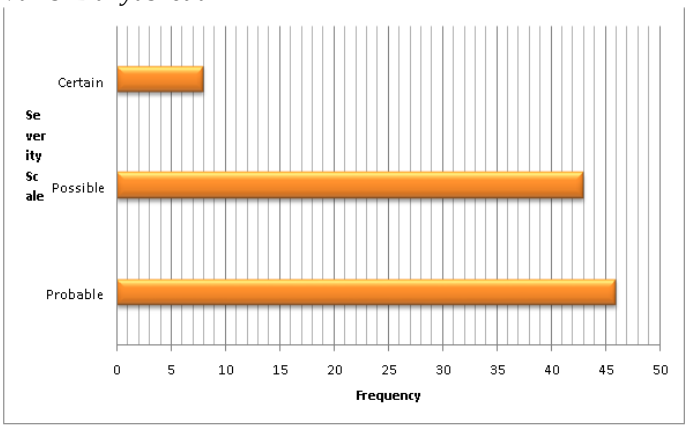

Figure 3: Causality of ADRs induced by Anti-TB drugs according to Naranjo algorithm

Evaluation of the severity of ADRs indicated that most of the ADRs detected had severity in level 1 (38.14%) and 4a (35.05%). (Table 5)

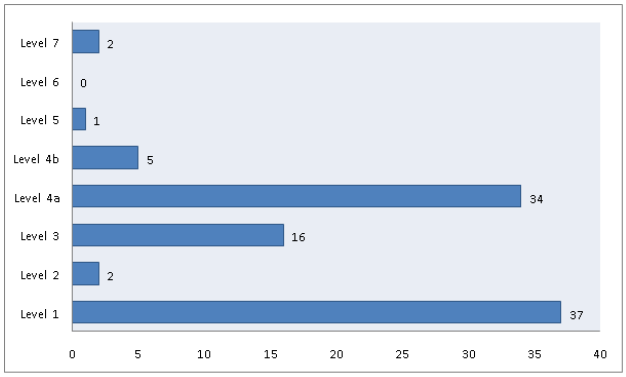

Figure 4: Severity of ADRs induced by Anti-TB drugs.

Table 5: Severity of ADRs induced by Anti-TB drugs

S.No	Severity	Number	Percentage
01	Level 1	37	38.14
02	Level 2	02	2.06
03	Level 3	16	16.49
04	Level 4a	34	35.05
05	Level 4b	05	5.15
06	Level 5	01	1.03
07	Level 6	0	0
08	Level 7	02	2.06

Discussion

Among 100 patients entered the study, 53(53%) patients showed at least one adverse reaction. This relatively high percentage of occurring adverse reactions indicates that there is a need for more evaluation of susceptibility of patients for developing Anti-TB induced ADRs. Daphne Yee et al,[17] conducted a study to estimate the incidence and risk factors of major side effects from first line Anti-TB drugs between. They evaluated 430 patients treated with Anti-TB drugs between 1990-1999. The results of the study showed that the incidence of all major adverse effects was 1.48 per 100 person's month of exposure. The occurrence of any major side effect in the study was associated with female sex. It does appear that with Anti-TB drugs used in this study the rate of ADRs increases with increased age [17-19].

In our study the major cause of admission was adverse drug reactions in 15.9% of patients. In similar study conducted in Iranian population hospitalized in general medical ward, ADR has been reported the cause of admission for 8% patients.

In our study Hepatitis was observed in 25 (25.77%) patients, leading to the death of 2 patients. It has been estimated that 10 to 20% of INH receptors developed elevated liver enzymes.[18] However, In case of mild, subclinical hepatic damage, the reaction does not progress to evident hepatitis and recover completely despite of the continuing INH therapy. In contrast, if clinical symptoms occur, severe Hepatocellular toxicity could be happened which is associated with a higher fatality rate than that of patients whose INH was discontinued immediately[20].

Some evidence initially suggested that concurrent use of INH and rifampicin might lead to a greater risk of hepatotoxicity. It is believed that Rifampicin can induce the metabolism of INH to hepatotoxins. A Meta-analysis conducted by Steele et al, looking at the incidence of hepatitis in all studies between 1966 and 1989 using regimens contained INH without Rifampicin, Rifampicin without INH and regimens containing both drugs, revealed that the incidence of clinical hepatitis was greater in regimen containing both the drugs [21-23]. The authors suggested that this effect was additive not synergistic, therefore the use of the two drugs together, is not contraindicated. However, caution should be taken in high risk individuals such as elderly, alcoholics, those taking additional hepatotoxic agents and those with pre-existing liver diseases. Rifampicin usually causes cholestasis, which leads to raise alkaline phosphatase and bilirubin. Liver toxicities can be the major side effect of all three main anti-TB drugs, Isoniazid, Rifampicin and Pyrazinamide [24].

Conclusion

In conclusion, Anti-TB drugs could cause significant adverse effects both in quantity and severity. These reactions may lead to hospitalization, prolonged hospital stay and even death. Asian people may develop more frequently severe adverse reactions, such as hepatitis, induced by this class of medicines [25]. These results suggest that the protocol may need some revision to prevent fatal hepatotoxicity. To confirm this hypothesis many more studies with large population is needed.

Conflict of Interests

The authors declare no conflict of interest

Ethics Approval: Not applicable

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AI Tool Declaration

The authors declare that no AI and related tools are used to write the scientific content of this manuscript.

References

[1] Xia YY, Hu DY, Liu FY, Wang XM, Yuan YL, Tu de H, et al. Design of the anti-tuberculosis drugs induced

adverse reactions in China National tuberculosis prevention and control scheme study (ADACS). BMC Public Health. 2010;10:267.

[2] Gholami K, Kamali E, Hajiabdolbaghi M, Shalviri G. Evaluation of anti-tuberculosis induced adverse reactions in hospitalized patients. Pharm Pract (Granada). 2006;4(3):134-8.

[3] Mishra S, Jena M, Jena B, Mishra SS. A study of anti-tubercular drug induced adverse reactions in patients attending pulmonary medicine Department of a Tertiary Care Teaching Hospital. Int J Pharm Sci Rev Res. 2013; 21(2):308-11.

[4] Mahendra Kumar BJ, Mathew S, Ramesh S, Maheshwari DM, Hymavathi R, Srikanth MS.Causality Assessment of Adverse Drug Reactions in Tuberculosis Patients who are on Directly Observed Treatment Short Course Strategy in Mysore District. Indian Journal of Pharmacy Practice, 2013; 6(4):22-26.

[5] Nanda GS, Singh H, Sharma B, Arora A. Adverse Reactions Due to Directly Observed Treatment Short Course Therapy: An Indian Prospective Study. IAIM, 2016; 3(1):6-12.

[6] Nemagouda S. The Antitubercular Drug Induced Adverse Effects in Registered Cases under RNTCP – Dots Programme in Bijapur.Journal of Evolution of Medical and Dental Sciences, 2014; 3(19):5255-5262.

[7] Ramanath KV, Ramesh.S. A study on assessment of Adverse Drug Reactions in Tuberculosis patients. American Journal of Pharmtech Research, 2012; 2(2): 584-592.

[8] Revanna S, Harish CK, Amol G. Adverse drug reaction monitoring of anti-tubercular drugs at tertiary care medical college hospital: prospective study. Int J Basic Clin Pharmacol, 2017; 6(11):2738-2742.

[9] Sadiq S, Khajuria V, Vishal RT, Mahajan A, Singh JB. Adverse drug reaction profile in patients on Anti-tubercular treatment alone and in combination with highly active antiretroviral therapy. Journal of Clinical and Diagnostic Research, 2015; 9(10):FC01-FC04.

[10] Sinha K, Marak ITR, Singh WA. ADR in tuberculosis patients due to directly observed treatment strategy therapy experience at an outpatient clinic of a teaching hospital in the city of Imphal, Manipur, India. The journal of association of chest physicians, 2013; 1(2):50-53.

[11] Edoh D, Adjei R. Rapid assessment of a National tuberculosis (TB) control Programme in Eastern Ghana. Afr J Health Sci. 2002;9(3-4):159-64.

[12] Sinha K, Marak IR, Singh WA. Adverse drug reactions in tuberculosis patients due to directly observed treatment strategy therapy: Experience at an outpatient clinic of a teaching hospital in the city of Imphal, Manipur, India. J Assoc Chest Physicians. 2013;1:50-3.

[13] Dalal NP, Karandikar YS, Pandit VA. Safety evaluation of directly observed treatment short course (DOTS) regimen in a tertiary care hospital, Pune. Int J Basic Clin Pharmacol. 2014;3:369-76.

[14] Burman WJ, Reves RR. Hepatotoxicity from Rifampin plus Pyrazinamide. Lessons for Policymakers and Messages for Care Providers. Am J Respir Crit Care Med. 2001;164:1112–3.

[15] Sharma SK, Balamurgan A, Saha PK, Pandey RM, Mehra NK. Evaluation of clinical and immunogenetic risk factors for the development of hepatotoxicity during Antituberculosis treatment. Am J Respir Crit Care Med. 2002;166:916–9.

[16] Yee D, Valiquette C, Pelletier M, Parisien I, Rocher I, Menzies D. Incidence of Serious Side Effects from First-Line Antituberculosis Drugs among Patients Treated for Active Tuberculosis. Am J Resp Crit Care Med. 2003;167:1472–7.

[17] Farazi A, Sofian M, Jabbariasi M, Keshavarz S.Adverse Reactions to Antituberculosis Drugs in Iranian Tuberculosis Patients. Tuberculosis Research and Treatment, 2014; 1-6.

[18] Gholami K, Kamali E, Hajiabdolbagh M, Shalviri G. Evaluation of anti-tuberculosis induced adverse reactions in hospitalized patients. Pharmacy Practice, 2006; 4(3):134-138.

[19] Hema NG, Bhuvana KB, Virupaksha HM.Critical Assessment of Adverse drug Reactions to Antitubercular Drugs in a Government Teaching Hospital. IJBMS, 2013; 4(2):60-67.

[20] Hassan MK, Siddique A, Karadiya RK, Chakraborty A.Incidence of Adverse Drug Reactions Among the Tuberculosis Patients Treated Under Directly Observed Treatment Short course (DOTS) regimen in North India.Indian Journal of Applied Research, 2016; 6(7):598-600.

[21] Honnaddi UC, Honnaddi MU, Tharangini SR, Hossain T, Somani R. Adverse Drug Reactions to First Line Anti-Tubercular Drugs-A Pharmacovigilance Study. IJPR, 2016; 6(2):51-54.

[22] Kinjal P, Mira D, Samidh S, Jigar P, Kapadia J, Dikshit R. An analysis of serious adverse drug reactions at a tertiary care teaching hospital. Perspect Clin Res 2016; 7(4):81-86.

[23] Kishore PV, Palaian S, Ojha P, Shankar PR.Pattern of adverse drug reactions experienced by tuberculosis patients in a tertiary care teaching hospital in Western Nepal. Pakisthan journal of pharmaceutical sciences, 2008; 21(1):140-143.

[24] Mishra S, Jena M, Jena B, Mishra SS. A study of Anti-tubercular drug induced adverse drug reactions in patient's pulmonary medicine department of a tertiary care teaching hospital. Int J Pharm Sci Rev Res, 2013; 21(2):308-311.

[25] Maqussod M, Khan FA, Swaroop A.A Study on Incidence of Adverse Drug Reaction of Anti-Tubercular Drugs in New Cases of Pulmonary Tuberculosis in a Tertiary care Teaching Hospital. IJMRP, 2016; 2(3):53-56.